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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,923	04/30/2001	Patrick Kennedy	1022-11	4246

7590

12/26/2002

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/26/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,923

Applicant(s)

Kennedy, P.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 17, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-22, 24-28, and 30-32 is/are pending in the application.
- 4a) Of the above, claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10-19, 21, 22, 24-28, and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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DETAILED ACTION

It is noted that Applicant has indicated that Claims 4-8, 10-19, 21-22, 24-28 and 30-32 remain pending (p.6, Remarks). However, it cannot be found where claims 1-3 and 20 were canceled in the application. Thus, Office's records indicate that claims 1-8, 10-22, 24-28 and 30-32 are pending in the application. If claims 1-3 and 20 have been canceled, Applicant is asked to point out where in the application this occurred in order for the Office to correct the record because this response indicating the pending claims was not executed on the record.

Claims 1-3 and 20 were withdrawn from further consideration on the merits as being drawn to a non-elected invention in Paper No. 3.

Claims 4-19 and 21-32 have been presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

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Claims 4, 11, 13, 19, 21, 22 and 31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 remains rejected for the recitation of 'walnut shells' and 'plastic materials' which both lack antecedent basis in the claim because the claim stated 'ingredient' which is singular.

Claims 11 and 31 remain rejected for the recitation of 'antiseptic preparations' antimicrobial agents' 'disinfectants' borates, oils, plants or animals, pain reducers, analgesic ingredients' and 'antihistamine ingredients'. All of these terms lack antecedent basis in both claims since the claims previously stated 'ingredient' which is singular.

Claim Rejections - 35 USC § 102

Claims 21-22, 24-26, 28, and 30-32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Product Alert (1998) in light of Miner (2002) for the reasons set forth in the previous Office Action.

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Applicant's arguments were fully considered, but not found persuasive.

Applicant's principal argument is that the composition as Instantly claimed is not the same composition as disclosed by Product Alert (p.8, Arguments). Applicant has listed what the composition of the Instant claims will do on p. 8 of the Arguments, and argued that Product Alert was not specifically formulated to remove or treat insect bites and stings (p.9-Arguments). Additionally, Applicant cites the case law of *Leinoff V. Milona & Sons, R.C.A. Corp. V. Applied Digital Data Systems, Inc. and W.L.Gore & Associates, Inc.v.Garlock*. Applicants argue that "Since there are numerous additional ingredients in NDM, which result in a totally different function and use as well as inhibiting the effectiveness for use to perform the objective of the present claimed invention, it is respectfully submitted that the pharmaceutical composition of the present claimed invention cannot be said to be "anticipated" by Origin's NDM cosmetic composition" (p.9, Arguments).

It is first noted that the intended use, in the Instant claims has been analyzed for patentable weight. In the Instant case, it is deemed that the intended use does not materially change the composition. It is also deemed that the additional ingredients present in the Origin's product would not preclude the composition from treating insect bites because the ground material found in the composition would pose some relief to

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bites and stings when rubbed onto an insect bite. It is also noted that the intended use does not *limit* the claims, since the intended use does not materially change the composition. Thus, the patentability or non-patentability of the claims lies in the body of the claims, which comprises a pharmaceutical composition. The composition disclosed by Product Alert anticipates the claimed invention because the composition disclosed by Product Alert *contains each ingredient recited in the claimed invention*. Applicants contend that the product disclosed by Product Alert would not perform the intended use of the claimed invention. This assertion is unsubstantiated and is therefore not convincing.

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Further, the claims recite 'comprising'. Thus, the composition of the Instant claims can include numerous active and/or non-active ingredients.

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Claim Rejections - 35 USC § 103

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Product Alert (1998) in light of Miner (2002)* in view of Tseng et al. (US 5,716,634) for the reasoning set forth in the previous Office Action.

Applicant argues again that Product Alert did not obviate the Instant claims because the additional ingredients, i.e., lecithin, and propylene glycol stearate for example, would interfere with the process for neutralizing the venom (p.10-Arguments). Again, lacking sufficient evidence to the contrary, it is deemed that the additional ingredients disclosed by Product Alert do not preclude the composition from being used as a treatment for insect bites (please see *supra*). It is further noted that the claims do not recite anything regarding neutralizing venom. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that 'Tseng et al. Add nothing to Product Alert that would increase the ability of Product Alert to open the pores and neutralize the venom....' Again, Applicant is arguing features which are not present in the claimed invention. Tseng et al. provide motivation to shape polymers for cosmetic use into the particular

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mesh sizes as recited in the claimed invention: A rejection under 35 U.S.C. § 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration ***which is different from that which resulted in the claimed invention.*** (Emphasis added)Ex parte Raychem Corp., 17 U.S.P.Q. 2d 1417.

Thus, the composition as a whole would have been *prima facie* obvious to the ordinary artisan with the cited references before him.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

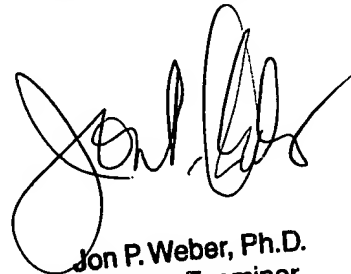
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner